510(k)
SUMMARY

SEP 2 4 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: k112449

Type of 510(k) Submission: Traditional

Submitter:

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Preparation Date:

January 11, 2011

Device Information:

Trade or Proprietary Name:
QuikResponse™ One Step Midstream Early Pregnancy Test

Common/Usual Name:
Lateral flow immunochromatographic assay for detection of human chorionic gonadotropin in human urine

Device Classification Name:
Immunoassay of human chorionic gonadotropin

Regulatory Name:
Human chorionic gonadotropin (hCG) Test System

Regulation Section: 21 CFR § 862. 1155

Regulatory Class: Class II

Product Code: LCX

Panel: Chemistry (75)

Predicate Devices:
QuikResponse™ One Step Midstream Early Pregnancy Test device test is substantially equivalent to the Firstresponse Pregnancy Test cleared by FDA (K030258) for its stated intended use.

Device Description:
The device consists of a plastic housing and test stick containing an immunochromatographic strip. The test pad contain colloidal gold conjugate with mouse monoclonal antibodies against beta subunit of hCG and test strip contain mouse monoclonal antibody against alpha subunit of hCG (test line)and goat anti-mouse polyclonal antibodies (Control line). The device is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine, in some cases as early as 3 days before the expected period.

Intended Use:
QuikResponse™ One Step Midstream Early Pregnancy Test is an over-the-counter urine hCG test which is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. The test detects pregnancy hormone, in some cases as early as 3 days before the expected period.

Comparison to Predicate Device(s):
Both devices (QuikResponse™ One Step Midstream Early Pregnancy Test device and Firstresponse Pregnancy Test) are for the qualitative determination of the human chorionic gonadotropin. Both test devices are single use devices.

Summary:
The information provided in this pre-market notification demonstrates that QuikResponse™ One Step Midstream Early Pregnancy Test device is substantially equivalent to Firstresponse Pregnancy Test. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supports substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Tianjin New Bay Bioresearch Co., Ltd.
c/o Biosource Technology
Hann-Ping Wang, Ph. D, Regulatory Consultant
5230 Via Primaria
Yorba Linda, CA 92886

SEP 24 2012

Re: k112449
Trade/Device Name: QuikResponse™ One Step Midstream Early Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: September 7, 2012
Received: September 11, 2012

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (k112449):

Device name: QuikResponse™ One Step Midstream Early Pregnancy Test.

Indications for Use:

QuikResponse™ One Step Midstream Early Pregnancy Test is an over-the-counter urine hCG test which is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. The test detects pregnancy hormone, in some cases as early as 3 days before the expected period.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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